Investigator_____ Date_____

PRE-STUDY QUESTIONNAIRE

Investigator's capability/interest

1. Indicate the number of clinical trials, either as Principal Investigator (PI) or Sub-Investigator (SI) you are currently enrolling in: 0-1 2-5 6-10 >10

2. Indicate the total number of clinical trials the investigator has served as PI in the last 5 years: 0-1 2-5 6-10 >10

3. Indicate the number of Sub-Investigators that will assist the PI in this trial: 0-1 2-5 6-10 >10

4. Does the PI have adequate time to fulfill study requirements and enrollment expectations of ___subjects in ___months? _____Yes _____No

5. Has the PI done studies with Covance Princeton before? _____ Yes _____ No

6. Has the PI done a study with Covance central labs before? _____Yes _____No

7. If the answer to Question #5 is yes, what is the name of the Covance contact person?

_____

Facilities

1. Indicate if your site has designated personnel to handle administrative functions such as:

   a) Contract Yes No

   b) Budget Yes No

   c) IRB Yes No

2. Indicate the number of days required for contract/budget approval:
   1-3 4-7 8-14 15-21 >21

   Name of contact _____ Telephone Number_____

3. Please provide the frequency of IRB meetings:
   Weekly Bimonthly Monthly Every two months

4. Indicate the days involved in turnaround time for local IRB approval (action) letter:
   1-3 4-7 8-14 15-21 >21

5. Can site use a Central IRB? Yes No

Source: https://www.industrydocuments.ucsf.edu/docs/hrkj0001

Investigator_____ Date_____

Staffing

1. Does your site have a dedicated research staff? Yes No

1. Indicate the number of Full Time Research RN's/Coordinators:
   1-3 4-6 7-10 >10

2. Indicate the number of Part Time Research RN's/Coordinators:
   1-3 4-6 7-10 >10

3. Indicate the number of studies assigned per Coordinator/Research RN per year:
   1-3 4-6 7-10 >10

4. Indicate the number of patients/subjects enrolled or screened for research in the past month:
   1-3 4-6 7-10 11-20 21-50 51-100 >100

5. Indicate the average length of employment of research staff (in years):
   1-3 4-6 7-10 >10

6. Does your site have the capabilities to process, handle and store (-70°C freezer) for PK blood samples? Yes No

7. Does your site have access to dry ice? Yes No

8. What are your hours of operation? _____

9. Is your site able to see subjects on the weekends? Yes No

10. Please indicate the name of an appropriate contact person at your site:

    Name: _____

    Telephone Number: _____

Source: https://www.industrydocuments.ucsf.edu/docs/hrkj0001

Investigator_____ Date_____

Protocol/Enrollment

1. Indicate the number of subjects/patients seen at your site per year: _____
2. Indicate the estimated number of subjects you can enroll per month in this study: _____
3. Please indicate sources you will utilize to identify subjects for this study:
   _____
   _____
   _____
4. Will the research studies that are currently open, compete for this subject population?

   Yes No
5. What challenges do you perceive in conducting this trial at your site?
   _____
   _____
   _____
6. Please indicate the computer capabilities of your site: i.e. programs used, operating system.
   _____
   _____
7. Does your site have access to the internet? Yes No
8. Who is the internet provider used _____
9. Does your site have access to a copy machine? Yes No
10. Does your site have access to a fax machine? Yes No
11. Does your site have access to an Airborne account? Yes No
11. How many subjects can you see for this study daily, for screening? _____
12. How many subjects can you see for this study daily, for enrollment? _____
13. Have any of your coordinators done remote data entry? Yes No

Source: https://www.industrydocuments.ucsf.edu/docs/hrkj0001

14. Investigator_____ Date_____

Please Complete and Fax within 3 Working Days to:

Mary Larson, RN, CCRC, CCRP

Senior Clinical Project Manager

Covance Clinical Research Unit

309 West Washington Avenue

Suite 4 East

Madison, WI 53703

Fax Number: 608-661-8169

Telephone Number: 608-283-5698

Source: https://www.industrydocuments.ucsf.edu/docs/hrkj0001